



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

The Standards Institution of Israel Electrical and Electronics Laboratory

Corporate Location
42 Chaim Levanon Street
Tel Aviv, 6997701 Israel

Fulfills the requirements of

ISO/IEC 17025:2017

and the

**FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety
and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and
Laboratory Medical Equipment**

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 14 May 2028

Certificate Number: AT-1359.01



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

The Standards Institution of Israel Electrical and Electronics Laboratory

Corporate Location
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TESTING

ISO/IEC 17025 Accreditation Granted: **14 May 2026**

Certificate Number: **AT-1359.01** Certificate Expiry Date: **14 May 2028**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment and Systems	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	19-46, ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [incl. AMD2:2021] 19-49, IEC 60601-1 Edition 3.2:2020-08 CONSOLIDATED VERSION	Entire Standard except spark test
Electrical Equipment for Measurement Control & Laboratory Use	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	19-34, IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	Entire Standard

This Scope of Accreditation, version 001, was last updated on: 14 May 2026 and is valid only when accompanied by the Certificate.

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Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment and Systems	Electromagnetic Compatibility Emissions & Immunity	19-36, ANSI AAMI IEC 60601-1-2:2014 [including AMD 1:2021] IEC 60601-1-2 Edition 4.1:2020-09 CONSOLIDATED VERSION	Excluding Figure 3 and Sub Clause 8.9, Table 8 per partial FDA recognition
Medical Electrical diagnostic X-ray Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-336, IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Entire Standard
Medical Electrical Equipment	Usability Review	5-132, IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Entire Standard
Alarm systems in Medical Electrical Equipment and medical electrical systems	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	5-131, ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021] IEC 60601-1-8 Edition 2.2:2020-07 CONSOLIDATED VERSION	Entire Standard
Development of physiologic closed-loop controllers in Medical Electrical Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	19-37, IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	Entire Standard
Medical Electrical Equipment and Systems for use in the Home Healthcare Environment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	19-38, IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Excluding Note 2 to entry in Sub-clause 3.1 per partial FDA recognition

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment and Systems for use in the Home Healthcare Environment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	19-47, ANSI AAMI HA60601-1-11: 20215 [Including AMD1:2021]	Entire Standard
Medical Electrical Equipment and Systems for use in Emergency Medical Services Environment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	19-39, ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021] IEC 60601-1-12 Edition 1.1:2020-07 CONSOLIDATED VERSION	Entire Standard
Electrosurgical Generators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-389, IEC 60601-2-2 Edition 6.0 2017-03 ANSI AMI 60601-2-2:2017	Excluding Subclauses 202.7 and 202.8 per partial FDA recognition
Ultrasonic physiotherapy equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-205, IEC 60601-2-5 Edition 3.0 2009-07	Entire Standard
Nerve and Muscle Stimulators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	17-16, IEC 60601-2-10 Edition 2.1 2016-04	Entire Standard
Endoscopic Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	9-114, IEC 60601-2-18 Edition 3.0 2009-08	Entire Standard

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Infant incubators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-385, IEC 60601-2-19 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Infant transport incubators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-386, IEC 60601-2-20 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Infant radiant warmers	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-388, IEC 60601-2-21 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Surgical, cosmetic, therapeutic and diagnostic laser equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-268, IEC 60601-2-22 Edition 3.1 2012-10	Entire Standard
Surgical, cosmetic, therapeutic and diagnostic laser equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-356, IEC 60601-2-22 Edition 4.0 2019-11	Entire Standard
Electrocardiographs	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	3-105, IEC 60601-2-25 Edition 2.0 2011-10 ANSI AAMI IEC 60601-2-25:2011/ (R)2016	Excluding Clauses 201.12.1.101.2, 201.12.1.103.3.1, 201.12.1.103.3.2 per partial FDA recognition

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Electrocardiographic Monitoring Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	3-126, IEC 60601-2-27 Edition 3.0 2011-03 ANSI AAMI IEC 60601-2-27:2011/ (R)2016	Entire Standard
Magnetic resonance equipment for medical diagnosis	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-347, IEC 60601-2-33 Edition 4.0 2022-08	Entire Standard
Invasive Blood Pressure Monitoring Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	3-115, IEC 60601-2-34 Edition 3.0 2011-05	Entire Standard
Ultrasonic Medical Diagnostic and Monitoring Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-293, IEC 60601-2-37 Edition 2.1 2015	Entire Standard
X-ray equipment for interventional procedures	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-329, IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION	Entire Standard
X-ray equipment for computed tomography	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-302, IEC 60601-2-44 Edition 3.2:2016	Excluding Sub-clause 203.108 per partial FDA recognition

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Mammographic X-ray equipment and mammographic stereotactic devices	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-294, IEC 60601-2-45 Edition 3.1 2015	Entire Standard
Ambulatory electrocardiographic systems	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	3-155, IEC 60601-2-47 Edition 2.0 2012-02	Entire Standard
Infant phototherapy equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-387, IEC 60601-2-50 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Medical Beds	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-321, IEC 60601-2-52 Edition 1.0 2009-12	Entire Standard
X-ray equipment for radiography and radioscopy	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-317, IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION 12-348, IEC 60601-2-54 Edition 2.0 2022-09	Entire Standard
Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-242, IEC 60601-2-57 Edition 1.0 2011-01	Entire Standard

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-355, IEC 60601-2-57 Edition 2.0 2023-07	Entire Standard
High intensity therapeutic ultrasound equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-281, IEC 60601-2-62 Edition 1.0 2013-07	Entire Standard
Dental Oral X-Ray Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-310, IEC 60601-2-63 Edition 1.1 2017-07 CONSOLIDATED VERSION	Entire Standard
Dental Oral X-Ray Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-311, IEC 60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION	Entire Standard
X-ray-based image-guided radiotherapy equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	12-319, IEC 60601-2-68 Edition 1.0 -09	Entire Standard
Critical care ventilators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1.149, ISO 80601-2-12 Second Edition 2020-02	Entire Standard

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Critical care ventilators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1.146, ISO 80601-2-12 Third edition 2023-11	Entire Standard
Anesthetic workstation	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-141, ISO 80601-2-13 First edition 2011-08-11 [Including: Amendment 1 (2015) and Amendment 2 (2018)]	Entire Standard
Anesthetic workstation	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-165, ISO 80601-2-13 Second edition 2022-04	Entire Standard
Automated non-invasive sphygmomanometers	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	3-123, IEC 80601-2-30 Edition 2.0 2018-03	Excluding Clause 211.8.3.1 per partial FDA recognition
Heating devices using blankets pads or mattresses and intended for heating in medical use	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-390, IEC 80601-2-35 Edition 2.1 2016-04	Entire Standard
Respiratory gas monitors	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-140, ISO 80601-2-55 Second edition 2018-02	Entire Standard
Respiratory gas monitors	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-184, ISO 80601-2-55 Second edition 2018-02 [Including AMD1:2023]	Entire Standard

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Thermometers for body temperature measurement	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-421, ISO 80601-2-56 Second edition 2017-03	Entire Standard
Dental equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	4-262, IEC 80601-2-60 Edition 2.0 2019-06	Entire Standard
Pulse oximeter equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-139, ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	Excluding Clause 201.12.1.101.1 per partial FDA recognition
Oxygen concentrator equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-102, ISO 80601-2-69 First Edition 2014-07-15	Entire Standard
Sleep apnoea breathing therapy equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-115, ISO 80601-2-70 First Edition 2015-01-15	Entire Standard
Home healthcare environment ventilators for ventilator-dependent patients	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-105, ISO 80601-2-72 First edition 2015-04-11	Entire Standard
Respiratory humidifying equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-138, ISO 80601-2-74 First edition 2017-05	Entire Standard
Respiratory humidifying equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-177, ISO 80601-2-74 Second edition 2021-07	Entire Standard

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Robotically assisted surgical equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	6-438, IEC 80601-2-77 Edition 1.0 2019-07 ANSI AAMI IEC 80601-2-77:2020	Entire Standard
Ventilatory support equipment for ventilatory impairment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-143, ISO 80601-2-79 First edition 2018-07	Entire Standard
Ventilatory support equipment for ventilatory insufficiency	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	1-144, ISO 80601-2-80 First edition 2018-07	Entire Standard

Note:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment. Laboratories meeting these requirements are eligible to apply to participate in the FDA ASCA program. Participation in the FDA ASCA program can be confirmed by visiting their website <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories>.



Jason Stine, Vice President